UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/319,156 | 11/02/99 | PARANHOS-BACCALA | G 103514 |

OLIFF & BERRIDGE
PO BOX 19928
ALEXANDRIA VA 22320

HM12/0216

| EXAMINER | |
|---|---|
| PARKIN, J | |
| ART UNIT | PAPER NUMBER |
| 1648 | 9 |

DATE MAILED: 02/16/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/319,156 | Paranhos-Baccala, G., et al. |
| **Examiner** | **Group Art Unit** |
| Jeffrey S. Parkin, Ph.D. | 1648 |

☒ Responsive to communication(s) filed on *2 Jun 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-26* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-26* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## Lack of Unity

### *Unity of Invention*

1. This application was filed under 35 U.S.C. § 371 and is subject to unity of invention practice pursuant to 35 U.S.C. § 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In accordance with 37 C.F.R. § 1.499, applicants are required, in response to this action, to elect a single invention to which the claims must be restricted.

a. Group I, claims 1-17 and 22, drawn to **nucleic acids** corresponding to various regions of the retroviral genome.

b. Group II, claims 18-21, drawn to nucleic acid **probes** and **primers** derived from various regions of the retroviral genome.

c. Group III, claims 23 and 24, drawn to different retroviral structural **proteins**.

d. Group IV, claim 25, drawn to a **diagnostic composition** comprising nucleic acid fragments corresponding to various regions of the retroviral genome.

e. Group V, claim 25, drawn to a **prophylactic or therapeutic composition** comprising nucleic acid fragments corresponding to various regions of the retroviral genome.

f. Group VI, claim 26, drawn to **detection methods** employing nucleic acid fragments corresponding to various regions of the retroviral genome.

**In addition to the groups identified *supra*, applicants are required to identify and elect only those nucleotide sequences corresponding to a single and specific structural (i.e., gag, pol, or env) and regulatory region (i.e., LTR) of the viral genome.** For instance, if Group I is elected, applicants should pick a specific structural or regulatory region (i.e., the *pol* gene) and clearly indicate which nucleotide sequences (i.e., SEQ ID NO.: 112) correspond to

the elected region. If Group III is elected, applicants should pick a specific structural protein (i.e., the Env protein) and clearly indicate which nucleotide sequences encode the region of interest (i.e., SEQ ID NO.: 114?). The claims will only be examined to the extent they read on the elected structural or regulatory region. Due to the confusing nature of the sequence disclosure, the Examiner was unable to clearly ascertain the structural/regulatory features of all the SEQ ID NOS. set forth in the claims.

2. The inventions listed as Groups I-VI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the various groups identified *supra* are directed toward structurally and functionally different products (i.e., nucleic acids, primers, and proteins), compositions (i.e., diagnostic, therapeutic), and method of use. Each of the identified sequences is derived from a different region of the retroviral genome and will contain a unique structure and function (i.e., the Gag proteins form the virion capsid, the Pol proteins contain enzymatic functions required for reverse transcription and integration, and the Env proteins are required for viral entry). Moreover, the claimed invention also fails to make a contribution over the prior art as set forth in the ISA Chapter I search report which identified X and Y references.

***Claim Cancellation***

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

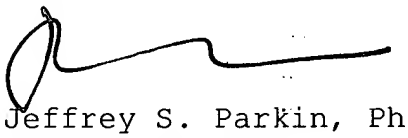
***Correspondence***

4. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

5. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

6. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

14 February, 2001